Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Proposal

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Efficacy Guidelines for Plant Protection Products

The aim of the regulation of pest control products is to ensure that pest control products offered for sale and use in Canada are safe to use, effective, and provide a demonstrated benefit or value. Value assessment is an important element of the pre-market evaluation of pest control products. Value assessments, as conducted by the Pest Management Regulatory Agency, consist of three components: assessments of efficacy, of economic benefits and competitiveness, and of a pest control product's contribution to sustainability.

The principles of efficacy evaluation described in this document are consistent with those established by major regulatory and scientific organizations internationally (e.g., the UK Department for Environment, Food and Rural Affairs, the U.S. Environmental Protection Agency, European and Mediterranean Plant Protection Organization, Australian National Registration Authority for Agricultural and Veterinary Chemicals).

The intent of these guidelines is to:

- outline the general requirements for conducting efficacy trials,
- describe procedures and criteria for efficacy data evaluation, and
- provide guidance in developing rationales for reduced data requirements.

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1.0 Introduction

The aim of the regulation of pest control products is to ensure that pest control products offered for sale and use in Canada are safe to use, effective, and provide a demonstrated benefit or value. Value assessment is an important element of the pre-market evaluation of pest control products. Value assessments, as conducted by the Pest Management Regulatory Agency (PMRA), consist of three components: assessments of efficacy, of economic benefits and competitiveness, and of a pest control product's contribution to sustainability.

Applicants for registration of pest control products must provide scientific information to support the efficacy of each control product for its intended purposes. This avoids the use of ineffective products or excessive dosages, which may increase pesticide residues in food and unnecessary exposure to applicators, bystanders, and the environment, and directly contributes to sustainable pest management and risk reduction. Efficacy evaluation (i.e., a determination of acceptable uses, rates, and practices) also provides a necessary baseline for future risk assessments and risk management decision-making.

Efficacy is defined as the ability of a pest control product to fulfil the claims made on the product label. It includes the extent of control of the pest problem and considers any adverse effects on the treated site. The purpose of the assessment of efficacy is to evaluate product performance in order to establish appropriate label claims and to demonstrate benefits to users at the lowest effective application rate. Pest control products must provide consistent results without unacceptable damage or injury to the crop or subsequent crops under normal use conditions. Data are required regarding:
(a) performance of the treatment on the target pest, (b) host tolerance to the treatment, and (c) effect on rotational crops.

The principles of efficacy evaluation described in this document are consistent with those established by major regulatory and scientific organizations internationally (e.g., the UK Department for Environment, Food and Rural Affairs (DEFRA), the U.S. Environmental Protection Agency (U.S. EPA), European and Mediterranean Plant Protection Organization (EPPO), Australian National Registration Authority for Agricultural and Veterinary Chemicals (NRA)).

1.1 Purpose

The intent of these guidelines:

- to outline the general requirements for conducting efficacy trials
- to describe procedures and criteria for efficacy data evaluation
- to provide guidance in developing rationales for reduced data requirements

A discussion of components of the value assessment which are not listed above may be found in other regulatory documents from the PMRA (DIR93-17, *Assessment of the Economic Benefits of Pesticides* and DIR99-06, *Voluntary Pesticide Resistance - Management Labelling Based on Target Site/Mode of Action*).

These guidelines consist of general principles which apply to chemical control products for plant protection. Additional guidance is available for pheromones (DIR97-02, *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals*) and microbial pest control products (DIR2001-02, *Guidelines for the Registration of Microbial Pest Control Agents and Products*) and guidance is in preparation for specific use sites (e.g., forestry, personal insect repellents, and plant growth regulators). PMRA Regulatory Directives (DIRs) and Regulatory Proposals (PROs) can be obtained through www.hc-sc.gc.ca/pmra-arla/.

Registrants may also wish to ask advice pertaining to the conduct of efficacy studies by means of a pre-submission consultation with PMRA staff.

1.2 Summary of Key Requirements

Key requirements are as follows:

- Each pest control claim must be supported by data or a scientific rationale for waiver of data.
- Data must be generated using sound scientific principles and experimental design and, where applicable, analysed using appropriate statistics.
- Data must demonstrate a consistent, commercially acceptable level of control under expected crop production conditions and pest management practices.
- Data should demonstrate a benefit to the user, normally in relation to a commercial standard.
- Trials should be conducted using the specific formulation and methods of application proposed for registration unless a sound rationale is provided for using alternative formulations/methods.
- Trials must be conducted over a range of relevant climatic and geographical regions typically over two use seasons. Trials conducted outside Canada are acceptable providing all other requirements are met.

- An adequate number of trials at proposed rates must be provided to demonstrate consistent performance at expected pest pressures. For insecticides, acaricides, and fungicides at least three trials are normally required; however, for major new uses more trials are typically necessary to establish confidence in efficacy claims and to establish appropriate rates. For herbicides ten trials are normally required for efficacy and ten dedicated tolerance trials are required to demonstrate crop tolerance.

- To demonstrate compatibility with sustainable pest management objectives, data should demonstrate that the lowest effective rate (LER) is proposed for registration.

- Where bridging arguments or requests for waiver of data are proposed to address specific requirements, these must be fully documented and based on scientific rationales.

- In the case of minor uses, the number of trials required may be reduced provided they are conducted as closely as possible to the proposed use pattern.

- Currently, efficacy trials do not need to be conducted in accordance with DIR98-01, *Good Laboratory Practices*, but it is expected that all trials will be conducted using good experimental practice.

2.0 General Principles for Conducting Efficacy Trials and Meeting Efficacy Data Requirements

2.1 General Data Requirements

The purpose of the assessment of pest control product efficacy is to evaluate product performance in order to establish appropriate label claims and the lowest effective application rate required to provide consistent results under normal use conditions without unacceptable damage or injury to the host/crop or subsequent host/crop. Sufficient data should be provided to permit an evaluation of the level, duration and consistency of control provided by the pest control product. Where possible the product should be compared to a registered commercial standard treatment (defined as a treatment which is registered in Canada, commonly used on the crop/pest combination, and applied in the trial at the registered rate). Relevant information is required to support all direct and implicit label claims relating to the use of the product. Accordingly, data submitted for review should represent the variety of conditions likely to occur in practical use in Canada, including a representative range of climatic, edaphic, crop, and agronomic conditions, with results representing two or more years of research in order to capture normal variations in climate.

Evidence should be submitted to show that the rate, timing, and method of application recommended give adequate control, protection, or have the intended effect in the range of circumstances likely to be encountered in practical use.

2.1.1 Source of Research

An efficacy data submission should consist of studies conducted by a number of research organizations. These may include researchers from the pesticide industry, private consultants, government, colleges, and universities. In developing data to support registration, the applicant should include independent research in their efficacy testing programs. Information from public domain, such as published papers from refereed journals, may be submitted to supplement a data package consisting of experimental trial work.

2.1.2 Performance

The aim of the evaluation of data is to ensure that the proposed label claims are supported and reflect the actual performance of the product while providing demonstrated benefit to the end user. Product performance should typically be comparable to a commercially registered standard, if available, but may under some circumstances be acceptable with a lower level of control when additional benefits are demonstrated (e.g., as a tool in an Integrated Pest Management (IPM) program).

Performance assessments may involve qualitative and/or quantitative assessments. Where appropriate, the degree of control should be reported as a percentage relative to an untreated control. In cases where other rating systems are used, the report should clearly define the conversion factor (from the rating system used to percent control).

A detailed discussion of performance standards for specific pesticide groups (i.e., herbicides, insecticides and acaricides, and fungicides) is provided in Section 2.2.

2.1.3 Lowest Effective Rate

Application of products at the lowest effective rate (LER) (also referred to as minimum effective dose) is an important means of achieving sustainable pest management objectives, avoiding or delaying resistance development, and avoiding unintentional effects on workers, bystanders, or the environment. Rate ranges must not be excessive but may allow for higher rates when, for example, pest pressures or environmental conditions warrant. Development of LER data is essential for all major pests. For the addition of minor uses the need for LER will be considered on a case-by-case basis. Refer to Section 3.4 "Application Rates and Lowest Effective Rate" for specific rate requirements.

2.1.4 Host Tolerance

The assessment of host tolerance may take the form of visual ratings by experienced personnel and by measurement of crop growth parameters and/or crop yield. The results may be reported in terms of percent tolerance, or injury, as compared to an untreated control or preferably to a control treatment (e.g., hand-weeded control for evaluation of herbicides). In cases where other rating systems are used, the report should clearly define the conversion factor (from the rating system used to a percent basis).

Host tolerance assessments should be made throughout the season as appropriate. It is essential to describe in the trial report the nature of any observed injury. In addition, where the results of a particular trial are anomalous to other observations, it is important to provide further details concerning possible reasons for the result such as environmental conditions experienced during the conduct of the trial. Where appropriate (e.g., for herbicide evaluations) yield of the proposed treatment should be reported as a percentage of either a hand-weeded treatment or a commercial control. For certain commodities where quality factors in addition to gross yield are of importance (e.g., vegetable crops), parameters such as size, quality, and appearance of edible parts or marketable yield, should be noted and described.

For requirements regarding crop tolerance trials for herbicides, see Section 3.13 "Crop Tolerance."

2.1.5 Rotational Crops

Field data are required to demonstrate the effect of a herbicide application on subsequent crops seeded in rotation. Label directions must clearly indicate the time interval when specific crops can be grown safely in succession, under various soil and weather conditions, and this interval should be supported by field trials. Rotational crop tolerance data are not usually required for insecticides, acaricides, and fungicides, but could be required on a case-by-case basis depending on the characteristics of the active ingredient (e.g., persistence).

Rotational cropping data must be representative of climatic and soil variation across the intended area of use of the product. Soil characteristics for the trial locations must be reported including soil zone and type (including percent sand, silt, and clay), percent organic matter, soil pH, and cation exchange capacity (CEC). The number of trials required to support rotational cropping directions will vary depending on the environmental fate characteristics of the herbicide as determined in the environmental assessment, and the range of climatic/soil variability across the intended area of use.

2.2 Specific Data Requirements

An adequate number of trials at proposed rates must be provided to demonstrate consistent performance at expected pest pressures. The number of trials required varies among insecticides, acaricides, herbicides, and fungicides, but in all cases must be sufficient to provide confidence in efficacy claims stated on the product label.

2.2.1 Herbicides

Generally, to demonstrate efficacy of an end use product containing a new active ingredient, consistent results from a minimum total of ten trials conducted over at least two years under representative conditions are required to support the label claim of any specific weed species. The minimum number of crop tolerance trials required for herbicides is discussed under Section 3.13 "Crop Tolerance."

Label claims for weed control are generally made on a species-by-species basis. Therefore, a report on broadleaved weed or grass control, with a list of weeds present, is not sufficient to support a specific label claim. Rather, the degree of control of each weed species in a test should be reported on a species-specific basis. Where more than one species of a weed is known by the same common name (e.g., pigweed, mallow), the binomial name should be provided so as to distinguish the species. To support a label claim for weed control, the degree of control should consistently reach a level which is considered commercially acceptable. Commercially acceptable levels may vary slightly depending on the use pattern and the weed problem, and the availability of alternatives. However, the level of control should, in all cases, be expected to provide a meaningful benefit to the user of the product. The various levels of efficacy, when evaluated over varying conditions across the intended area of use are defined in general terms in Table 1.

Table 1 Level of Control for Herbicides

Label claim	Performance Standards
Control	At least 80% reduction in weed stand and/or growth, when compared to untreated control plots.[1]
Suppression (or partial control)	A minimum of 60% reduction in weed stand and/or growth.
Top growth control	For perennial weeds where consistent 80% reduction of top growth has been demonstrated.

[1] This level of control may not be acceptable for certain weed/crop combinations where few or no weed escapes can be tolerated (e.g., for crop quality considerations), or where any weed seed contamination (e.g., cleavers in canola or alfalfa seed) could downgrade marketability of the crop seed.

Efficacy assessments should be conducted throughout the season following application, with evaluations generally preferred to be conducted at 7–14, 21–35 and 42–56 days after treatment (DAT). If the claim for season-long control is proposed on the label, or perennial weed control is claimed, an efficacy evaluation conducted late in the season near crop maturity is essential to support this claim. Crop tolerance assessment should be conducted at similar timings. For perennial crops (e.g., forage crops, ginseng) the effect of the herbicide treatment should be monitored until the following year.

Timing of application for post emergence treatments requires data to demonstrate crop tolerance of all crops treated at the proposed leaf staging. In addition, efficacy of the product on weeds listed for control on the product label must be demonstrated at the appropriate stage of growth (i.e., as indicated on the product label). Furthermore, control product use may be integrated into crop production systems which differ in the level of soil tillage performed, ranging from the absence of tillage (no till, direct seed), through intermediate (minimum till), to conventional (at least two tillage operations). The proposed label use of a product (e.g., herbicide) in no-till or direct seeding production systems must be supported by trial data so it is important to include information concerning the crop production system in the trial reports.

2.2.2 Insecticides and acaricides

To provide representative data over the varying conditions of the proposed use, at least three studies or trials per crop/pest combination conducted under the full range of possible growing conditions are generally required. Typically, more than the minimum number of trials is required to support use claims and to establish lowest effective rate for a major use.

For agricultural and forestry uses, the studies must be conducted over at least two years, in areas that represent the major geographical regions where the product is intended to be used. The studies should also take into account possible differences in product performance under various pest population pressures. Artificially infested plots may be used where insufficient numbers of pests occur naturally. Regional variations in climate, insect resistance, soils, application methods, and/or cultural practices may necessitate more than three trials to adequately demonstrate efficacy in all areas and conditions of intended use.

Range-finding or dose-response field studies which clearly demonstrate the lowest effective rate must be included. Refer to Section 3.4 "Application Rates and Lowest Effective Rate." Studies with indicator pest species may be considered in lieu of range-finding data requirements for similar species.

Each site/pest or crop/pest combination on the proposed product label must be assessed separately. The use of data for arthropods of a few species to support efficacy claims for a whole species complex, family, or higher taxon (e.g., "leafrollers," "aphids," "mites," "flies"), or data from one crop to support claims for whole crop groups (e.g., "cole crops"), will only be considered in lieu of providing data for each site/pest or crop/pest combination if supported by an adequate scientific rationale.

Level of Control – Arthropod Pests

The submitted efficacy information is evaluated to ensure the label claims are supported and reflect the actual performance of the product. The performance provided should typically match or exceed that of a commercially acceptable standard treatment. The following guidance broadly reflects the currently applied performance requirements for label claims. This is not a rigid framework for label claims and, if other claims are considered appropriate to the crop/pest situation, they may be proposed.

A performance claim for "control" of an arthropod pest must be supported by efficacy data which demonstrates that the product, when applied in accordance with the label directions, consistently reduces pest numbers or pest damage to a commercially acceptable level.

Generally, there is no single standard definable as "commercially acceptable control" for reduction in numbers of pests or damage, that is applicable to all pest management scenarios. The pest management objective or the specific level of reduction in pest numbers or damage that is required to support a "control" claim depends on factors such as the type of damage caused by the pest, economic threshold levels for the particular pest, the tolerance for damage of the crop and the performance of other available commercial standard treatments. For example, for pests that cause direct damage to the marketable portion of the crop (e.g., codling moth on apples), a high level of pest reduction (e.g., >85%) would be required to ensure that the damage caused will be reduced to a level that will allow a marketable crop to support a "control" claim. For pests where the crop can withstand considerable levels of damage without a negative impact on marketable yield (e.g., early season flea beetle damage on canola), lower levels in reduction of pest numbers or damage can be considered to support a "control" claim.

Where efficacy data show that a product, when used as directed, does not consistently reduce pest populations or damage to a level typically required to achieve commercially acceptable control, a lesser label claim for "suppression" may be acceptable provided that the applicant can show that the demonstrated level of performance has value in a pest management program. In such cases, the product might not be as efficacious as available commercial standard treatment but other performance characteristics of the product might

contribute to its value as a pest management tool. A "suppression" claim might be considered in situations such as in the following examples:

- The product has a new or different mode of action (i.e., chemistry) which, when incorporated into a pest management strategy utilizing products with other modes of action, could contribute to management of pesticide resistance.

- The product has little or no negative impact on pest predators or parasites and, therefore, could be incorporated into an IPM program for management of the targeted pest and other pests.

- A treatment is applied for control of a primary pest; however, numbers of a secondary pest are also reduced by the treatment but not to levels which would normally be required to support a label claim for control. A "suppression" claim for the secondary pest could be supported if it could be shown that the level of efficacy against this secondary pest, when the product is applied for control of the primary pest, could reduce the need for other treatments for control of the secondary pest. (For example, populations of the secondary pest are suppressed to a level such that the economic threshold for the pest is not reached later in the season.)

Table 2 Level of Control for Insecticides and Acaricides

Label claim	Performance Standards
Control	To support a "control" claim for pests which cause direct damage to the marketable portion of the crop (e.g., codling moth on apples), a high level of pest reduction (e.g., >85%) would be required to ensure that the damage caused will be reduced to a level that will allow a marketable crop. Performance should be at least comparable to other commercial standards. For pests where the crop can withstand considerable levels of damage without a negative impact on marketable yield (e.g., early season flea beetle damage on canola), lower levels in reduction of pest numbers or damage can be considered to support a "control" claim.
Suppression (or partial control)	A label claim for "suppression" may be acceptable provided that the applicant can show that the demonstrated level of performance has value in a pest management program. In such cases, the product might not be as efficacious as available commercial standard treatments but other performance characteristics of the product might contribute to its value as a pest management tool.

2.2.3 Fungicides

Number of trials

As a general rule, a minimum of three trials conducted over at least two years is required to support each pathogen/crop combination. These trials must have sufficient disease present to challenge the fungicide and demonstrate that the fungicide reduces disease. Nevertheless, typically more trials are generated to establish confidence in the results. It is not always possible to ensure that there will be sufficient disease in host plants under field conditions, in which case it is necessary to carry out numerous trials in order to collect meaningful results from at least three of these. In cases where natural inoculum at field trial sites is unconfirmed, it is advisable to add artificial inoculum. Alternatively, controlled environment experiments may be used in which plants can be inoculated with target pathogens. However, these should be augmented with at least three field trials where the pathogen is observed to be present at some level, to demonstrate that the product offers benefits in crop development, yield, or quality, under commercial conditions.

Level of control

The efficacy of products should be demonstrated by a reduction of disease incidence or severity as shown in Table 3.

Table 3 Level of Control for Fungicides

Appropriate label claim	Performance standard
control	at least 60% disease reduction
suppression	40–60% disease reduction

For some diseases, particularly those affecting the quality of the crop, levels of consistent control higher than 60% will need to be demonstrated. For instance, in order to claim control of certain seed-borne pathogens (e.g., bunt, loose smut), a product needs to reduce disease incidence by at least 95%. The term "suppression" is defined here as "*consistent* control at a level which is not optimal but is still of commercial benefit." The threshold of acceptable disease reduction for this claim depends on the disease and crop, the efficacy of alternative control measures, and the expected impact of a proposed fungicide product on crop yield or quality. "Suppression" is not used for products which show highly variable performance between trials. Product efficacy based on less than 40% disease reduction is rarely acceptable and would require a detailed rationale to demonstrate that the product has value.

2.3 Reduced Data Requirements

Proposals for uses of certain new or amended pest control products may in some cases be supported by fewer data than the basic requirements noted in Section 2.2 (i.e., in instances involving bridging data, extrapolation or minor uses). This approach is particularly applicable to situations of proposed label changes which may be directly comparable to existing label uses that are known and already supported by a full efficacy package (e.g., adding another crop to an established pest claim already made on several crops in that group).

It should be noted that both product efficacy and crop tolerance of the amended product will need to be addressed. For specific situations not described below where a reduced data package could be appropriate, it is best to contact the PMRA at the planning stage of the research program for advice on whether an alternative approach to the full data package is likely to be acceptable. In all cases, the chosen approach to meeting data requirements should be clearly stated in the value summary.

2.3.1 Minor Formulation Changes

Certain minor changes in formulation *do not* require additional efficacy or crop tolerance data, specifically:

- change in source of active ingredient
- change in substances added to preserve the formulation in the container or to improve safety to non-targets, e.g., preservatives and anti-freeze — except for vertebrate control bait products
- changes in substances used to identify the formulation, e.g., dyes
- in general, changes of less than 10% in the amount of any formulation component including the active ingredient
- formulation changes to herbicides applied pre-emergence, except for granular or slow-release products
- fumigants where the new formulation is shown to release the gaseous active at a similar rate and same levels as the registered formulation

2.3.2 Bridging Data

Bridging data are data from a set of trials directly comparing a proposed new use to either a use accepted on a registered product label, or another proposed use which is supported by a full data set. The use of bridging data is appropriate only where a full data set has been provided as a basis for a comparison, and is more likely to be acceptable if performance has been well established on a range of crops or pest control claims. Comparative (side-by-side) trials can then be used to demonstrate that product efficacy and crop tolerance are equivalent for the original product or use and the proposed new product or use. For example, data in which the performance of a registered wettable powder formulation is comparable to performance of a new dry flowable formulation, could preclude the need for a separate full set of trials to support all use claims approved for the registered formulation for the proposed new formulation.

Equivalence of formulations need only be proved on a number of representative pest species which can then be used to support the inclusion of other pest species on the label. Equivalence is best demonstrated by providing comparative tests for the most challenging label claims, for instance on the most susceptible or most sensitive crops, or the pest species which are most difficult to control. Applicants are strongly encouraged to generate these data in a carefully planned program of bridging trials and to clearly communicate this comparison in trial reports and in the overall Value Summary.

Situations where the bridging approach may be applicable are described below, and include:

- resolved isomers of active ingredients
- new formulation/guarantee (same rate of applied active ingredient)
- coformulation of two or more registered active ingredients
- change in adjuvant or fertilizer
- change in carrier
- fertilizer impregnation
- change in spray application method (nozzle, pressure, water volume)

2.3.2.1 Resolved Isomers of Registered Active Ingredients

Although a resolved isomer is considered to be a new active ingredient (Category A submission) even if the racemic mixture of the active ingredient is already registered, reduced efficacy and tolerance data may be acceptable to support a product containing the isomer alone. In this case, the bridging trials should be composed of side-by-side evaluations of the racemic and the resolved isomer in order to make direct comparisons of both crop tolerance and efficacy. The crop/pest combinations chosen for evaluation should be representative of the registered (racemic) product label, including a variety of application timings and tank-mixes, if applicable. The field trials should be conducted in various locations (representative of the area of use) over a minimum of two years to account for environmental variability. If the two actives are shown to be equivalent in

these trials, further data would not be required for the remaining claims on the label for the isomer. For instance, tank-mix combinations could be supported by data with representative tank-mix partner products from each of the pesticide mode of action groups found on the proposed label (see DIR99-06) rather than testing every tank-mix partner on the label.

2.3.2.2 New Formulation/Guarantee (Same Rate of Applied Active Ingredient)

Formulation amendments, other than those included in the list of minor changes above, will usually require data. Examples include a substantial change in guarantee (>10%), substitution of formulants — particularly surfactants, or new formulation types (e.g., solution to wettable granule). The applicant must demonstrate that the new or amended formulation provides efficacy and crop tolerance equivalent to the original formulation. The planning of bridging trials is similar to that described for resolved isomers. Of particular concern for herbicides is the demonstration that crop tolerance and yield are not affected by the formulation change, especially for post-emergence herbicide products. In this case, bridging data must include two years of trials with each of the labelled crops. Acceptability of any other application times (PRE, PPI) on the label should also be demonstrated. For fungicides, insecticides and acaricides, bridging trials should show equivalence of formulations for those crop/pest combinations which present the most challenge to product performance and crop safety, and those claims which are most likely to be affected by the formulation changes.

2.3.2.3 Coformulation of Two or More Registered Active Ingredients

Bridging data may be used to support a coformulation consisting of two or more active ingredients that have been already registered together as a tank-mix. In such cases, efficacy and crop tolerance of the tank-mix is compared with that of the coformulation (premixed product) in side-by-side trials. Equivalency should be demonstrated for representative crops and pests.

2.3.2.4 Change in Adjuvant or Fertilizer

When a spray adjuvant is used with a pest control product for the first time, bridging trials should include a pest control product-alone treatment (without adjuvant) in order to assess the value of adding an adjuvant. Subsequent changes substituting one adjuvant for another can be accomplished by comparing the registered pest control product plus adjuvant system to the new proposed pest control product plus adjuvant system. The proposed maximum and minimum rates of adjuvant should be evaluated in these trials.

2.3.2.5 Change in Carrier

A change in spray solution carrier such as the use of a nitrogen solution or liquid fertilizer instead of water should be supported by bridging trials that demonstrate tolerance of labelled crops as well as efficacy on representative pest species. A data waiver request may also be considered if the product application is on soil rather than a post-emergence application. For fungicides, insecticides, and acaricides, a rationale may be sufficient to show that substitution of the inert carrier (for example, talc) is not critical to product efficacy or crop tolerance.

2.3.2.6 Fertilizer Impregnation

Bridging trials are required to demonstrate that the fertilizer-impregnated product is evenly distributed, resulting in equivalent efficacy and crop tolerance to the original formulation.

2.3.2.7 Change in Water Volume, Nozzle Type, or Spray Pressure

Bridging trials are required to demonstrate that changes in water volume, nozzle type or spray pressure will not affect efficacy or crop tolerance of post-emergence applied herbicides and most other product types. A data waiver request may also be considered for soil-applied herbicides.

2.3.3 Extrapolation and Crop/Pest Groupings

Extrapolation describes a situation where a full data set has been submitted for established or proposed pest control claim(s) and additional claims are then considered based primarily on scientific rationales and less frequently on additional data. Such rationales might demonstrate similarities between the supported and proposed claims with regard to pest biology, crop biology, and competitiveness or crop production methods. Taxonomic links alone are generally not sufficient evidence of similarity, but should be backed up by information on the biology of crop/pest interactions. The rationales will be reviewed on a case-by-case basis; however, general principles for each product type are described below, along with some examples of extrapolations that have been accepted in the past (Tables 4, 5, 6). These extrapolations may be used to support one or more crops or pests in a crop or pest grouping.

2.3.3.1 Herbicides

The required level of control of a particular weed and the level that can be achieved by a particular herbicide can be very different in different crops depending on a variety of factors. These factors include competitiveness of the crop, timing of weed control, times of sowing/planting, time/method of harvesting, and ease of separating crop seeds and weed seeds. If enough is known about the required levels of weed control, the competitiveness of the crop situation, and the factors affecting achievement of those

levels in both crops, it would be possible to make a well-argued case for extrapolating from one crop to another, as in the example above, taking competitiveness into account (Table 4).

Table 4 Extrapolation for weed control claims — some examples that have been accepted in the past

Situation	Crops	Notes
A: Field — competitive crops	Cereals, grassland, canola	Extrapolation accepted within group A and from B or C.
B: Field/horticultural — less competitive crops	Sugar beet, peas, flax	Extrapolation accepted within group B and from C, but not from A.
C: Other situations — non-competitive crops	Orchards	Extrapolation accepted within group C and possibly from B, but not from A.

2.3.3.2 Insecticides and acaricides

Depending on the mode of action and mobility of a compound, and the feeding habits of pests on plants, the efficacy of a pest control product can vary greatly. Some individual species of pests feed on different parts of different crops and this could affect the activity of a product against the same pest on different crops. In many cases it is possible to make a well-argued extrapolation that similarities between pests are such that data from one species can be considered representative of both species.

If data are available showing that an active substance can control a number of species of insects or mites feeding similarly on the plant (e.g., on the roots or within leaf mines) then extrapolation is more likely to be accepted. For other pests, it may be possible to argue that the timings of treatment are coincident. However it must be emphasised that the biology of the pest and its location on the plant have to be taken into account (Table 5).

Table 5 **Extrapolation for arthropod pest control claims — some examples that have been accepted in the past**

Pest species	Extrapolation		Comments
	From	To	
Codling moth	apples	pears	Pest biology, type of damage, host morphology, and application methods are similar for both crops. Data for this pest on apples would be adequate for extrapolation of control claims to pears.
Colorado potato beetle	tomato, eggplant	pepper	Pest biology, type of damage, host morphology, and application methods are similar for all 3 crops. Data for this pest on tomato and eggplant would be adequate for extrapolation to pepper.
Two-spotted spider mite	greenhouse ornamentals (roses, chrysanthemum, gerbera, begonia)	greenhouse ornamentals (carnation, geranium, poinsettia, hydrangia)	Pest biology and damage are similar on most greenhouse ornamental crops. Efficacy data on representative greenhouse ornamental crops would be adequate for extrapolation to other greenhouse ornamental crops provided that the application methods (e.g., equipment, spray volumes) are similar.
Grasshoppers	wheat, barley	oats, rye	Pest biology, type of damage, host morphology, and application methods are similar on all 4 crops. Data for this pest on wheat and barley would be adequate for extrapolation to oats and rye.

2.3.3.3 Fungicides

If data show that a fungicide controls certain diseases in a number of situations, then a case may be made that control of the same or a related disease is possible in other situations (Table 6). For example, if data are available showing consistently good control of *Pythium* on various cereal seeds, then it should be possible to extrapolate to additional cereals. In other cases, however, the epidemiology of a disease and the efficacy of control agents can be different on different host plants, or even on different parts of the same host plant. For example, *Fusarium graminearum* will have a different effect on wheat seedlings and on the developing head, and these two sets of symptoms may not be controlled by the same fungicide. In such cases extrapolation may not be acceptable.

Table 6 Extrapolation for disease control claims — some examples that have been accepted in the past.

Disease	From	To	Notes
Most diseases	Winter wheat	Spring wheat	- same pathogen for both - winter cereals tend to be subject to more disease pressure (need more evidence to extrapolate from spring back to winter cereal)
	Winter barley	Spring barley	
Non host-specific soil pathogens: *Pythium, Fusarium, Rhizoctonia, Penicillium*	one representative crop in agronomic group e.g., cereals, legumes	other crops in same group provided they are grown in similar field conditions	- applies to seed treatments only - acceptable crops must be known to have similar response to pathogen among varieties and species
Common bunt/ covered smut	wheat	barley	- similar pathogens, control of spores on seed surface
Botrytis	representative greenhouse ornamentals	various greenhouse ornamentals	- if data show consistent efficacy between the representative crops
Brown rot	representative stone fruit crops	various stone fruits	- if data show consistent efficacy between the representative crops
Certain diseases	canola	mustard	- if crop reaction to disease is similar for both

2.3.4 Minor Uses

The User Requested Minor Use Label Expansion (URMULE) program allows consideration of the expansion of a label for a new minor use of a pesticide for which the active ingredient and an end-use product are currently registered in Canada. (For further guidance refer to DIR2001-01, *User Requested Minor Use Label Expansion (URMULE)*) A minor use is defined as a necessary use of a pest control product for which the anticipated volume of sales is not sufficient to persuade the manufacturer to register and sell the product in Canada for this use. The decision on whether a proposal constitutes a "minor use" will be made by the PMRA.

Data on efficacy and crop tolerance are generally required to support minor uses, including the addition of a new crop, new pest, or new use pattern. The data may include trials reported in the literature or conducted specifically to support the use in Canada or under the IR-4 program in a corresponding region of the U.S.A. The number of trials required may be reduced, provided they are conducted as closely as possible to the proposed use pattern. For example, insecticides, acaricides, and fungicides require at least one valid trial with the proposed use to establish the appropriate rates and timing of product application specifically for that crop and pest. However, if results of this trial are not clear or the treatments differ from the proposed use by one or more factors, then additional trials are needed to confirm efficacy. For crop safety of herbicides, depending on the similarity of the requested crop to the currently registered crop, 4–5 crop tolerance trials may be required. If there is no comparable crop currently registered, then additional trials may be required. Similarly, if a requested weed is similar to currently registered weeds, then 4–5 efficacy trials should suffice. However, as with crops, if the requested weed is unique to the product's use pattern then additional efficacy trials may be necessary.

For minor use submissions the PMRA considers scientific rationales submitted in support of requests to extrapolate from efficacy data for registered crops to other crops within crop groupings and for registered pests to other pests within pest groupings. See Section 2.3.3 "Extrapolation" for examples of extrapolations across crop groupings. Pest groupings could include complexes of pests (e.g., leafrollers).

2.3.5 Other Situations Eligible for Reduced Data Requirements

2.3.5.1 Change in Application Technique (Ground, Aerial, Chemigation)

A limited number of field trials is required to demonstrate that product efficacy and crop tolerance are equivalent for the proposed and registered application techniques. The product should be tested for representative crops and pest control claims. Although side-by-side plots may not always be feasible, the separate trials should at least demonstrate that performance is not reduced by the proposed new application method. Several efficacy trials reporting on control of representative pest species would normally be adequate.

2.3.5.2 Addition of New Crop to a Registered End-Use Product

For herbicides, the number of trials required to support a proposal may be reduced when adding a new crop to a product label after initial registration when the spectrum of activity of the herbicide is well defined and predictable (e.g., graminicide on a broadleaf crop grown over an intermediate area). In cases where phytotoxicity is demonstrated to be low, 10 trials conducted over at least two years would usually be adequate to support the use of a registered herbicide on a new crop. When phytotoxicity of a herbicide is evident or variable (e.g., broadleaf herbicide applied to a broadleaf crop; graminicide applied to a cereal crop or forage grasses), additional trials should be conducted. Similarly, additional trials should be submitted to support the use of a herbicide on crops with extensive production area.

When a new crop is proposed for addition to the label of a herbicide already registered for use on a crop of similar agronomic character, a waiver request for efficacy data may be considered. As part of the waiver rationale all application parameters indicated on the label must remain unchanged (herbicide rate, weed growth stage, water volume). Crop tolerance data, however, may still need to be submitted as susceptibility of seemingly similar crops (e.g., durum wheat vs. spring wheat, sweet clover vs. red clover) may be quite different to the same herbicide.

For insecticides and acaricides, each site/pest or crop/pest combination on the proposed product label must be assessed separately. The use of data for arthropods of a few species to support efficacy claims for a whole species complex, family or higher taxon (e.g., "leafrollers," "aphids," "mites," "flies"), or data from one crop to support claims for whole crop groups (e.g., "cole crops"), will be considered in lieu of data for each site/pest or crop/pest combination if supported by an adequate scientific rationale.

For fungicides, the data required for addition of a claim for the same diseases on a new crop will depend on the similarity of the crop to those in the registered use pattern. Provided the pathogen produces similar symptoms on the new crop, in most cases extrapolation or bridging data will be appropriate.

2.3.5.3 Addition of a New Pest

In cases where the proposed claim is for a species of pest that is closely related to one claimed on a registered label, a reduced number of trials together with a rationale may be submitted to support this use.

2.3.5.4 Change in Timing of Application

A major agronomic change in the timing of application requires a full data package in support of both host tolerance and efficacy. Examples include shifting the timing of application from pre-plant to foliar, from pre-bloom to post-bloom, or from spring to fall. Data or a scientific rationale for a waiver must be submitted for all labelled crops and pests.

2.3.5.5 Change in Level of Control

An amendment to label claim from "suppression" to "control" for a given pest must be supported by data demonstrating the increase in level of efficacy. A change in the label reducing the pest claim from "control" to "suppression" may require supporting evidence to establish that the product continues to provide benefit.

3.0 Test Procedures for Generating Efficacy Data

3.1 Experimental Design

The objectives for trials and the criteria by which they are to be judged should be clearly defined; i.e., contrasts and hypotheses of interest should be specified in advance, preferably. Treatments in the trial should be selected carefully in keeping with established objectives. The timing of treatment should be reported both in terms of calendar date and the developmental stages of both the target pest(s) and/or host-site.

Efficacy tests should be designed so that appropriate statistical analysis of the data can be performed to ensure that any differences are attributable to the pest control product treatments. Typically a randomized complete block design or split plot design are employed in which the treatment plots are randomly distributed within each block. Other designs such as the completely randomized design may be used for trials conducted in completely homogeneous environments such as the greenhouse or growth chamber. The number of replicates required is usually a minimum of four but this may need to be higher in trials with greater levels of non-treatment variability. Non-treatment variables may include plot size, environmental gradients, the number of treatments, and the uniformity of distribution of the target organism over the experimental area.

While trials should include an untreated control and appropriate treatment control, the number of treatments in a trial should not be any greater than necessary. As the number of treatments increases, the accuracy of treatment comparisons declines due to increases in both the trial area and associated variation in uncontrolled variables (e.g., soil type or plant stand across the treated area). For most work/investigations it is preferred that the number of treatments and replications should be enough to ensure at least 12 degrees of freedom needed for proper statistical analysis.

Trials intended to support applications for registration should be designed, analysed and conducted in accordance with the following:

- "Guideline for the efficacy evaluation of plant protection products: Design and analysis of efficacy evaluation trials" PP 1/152(2) (EPPO, 1999), and

- "Guideline for the efficacy evaluation of plant protection products: Conduct and reporting of efficacy evaluation trials" PP 1/181(2) (EPPO, 1999).

Currently, efficacy trials in Canada do not need to be conducted in accordance with DIR98-01, *Good Laboratory Practices*, however, there is the expectation of good science. Further general information on experimental design can be found in Gomez and Gomez (1984) and Binns, *et al.* (2000). Guidance on the design of experiments for some crop/pest combinations can be found in individual EPPO guidelines (EPPO, 1997a,b, 1998, 1999).

3.2 Data Analysis and Interpretation

Whenever possible, test data should be analysed statistically as per the objectives and criteria established prior to conducting the experiment. Generally any quantitative data (such as yields, dry weight, counts, height) should be subjected to statistical analysis. Statistical analysis for visual assessments of damage (e.g., percent control) should be performed using appropriate non-parametric tests, or transformed appropriately to allow for the valid use of parametric statistical analysis.

The statistical methods used for analysis must be reported and supporting raw data provided. Significance, or $\propto = 0.05$, is considered standard in biology. It is desirable to provide tables of means and measures of dispersion such as standard errors and coefficients of variation, and test statistics such as F or t values. Orthogonal (independent) contrasts can be used to test hypotheses of interest. Multiple comparison tests can also be employed; however, their use with factorially structured data is not appropriate. The PMRA strongly recommends against the use of the Least Significant Difference (LSD) test for more than four treatments, and of Duncan's Multiple Range Test (DMRT).

Based on the analysis of experimental results, the researcher should draw conclusions from the trial and based on the results from a series of trials, an overall assessment of the performance of a product can be made. Conclusions must be clear, precise, and drawn on the basis of representative data. Further general information on experimental analysis and interpretation can be found in EPPO Guideline PP 1/152(2) (EPPO, 1999).

3.3 Test Substances and Compatibility Tests

The test substance should be the formulated product for which registration is sought. The essential treatments should be the product(s) to be evaluated which are applied at 0.5, 1, and 2× the proposed rate, a commercial standard treatment, and an untreated or water-treated control. Trials should be conducted using the formulation and methods of application proposed for registration. Data generated with similar formulations or with similar application methodology may be considered in some cases provided their relevance to the proposed product is explained.

Where several similar formulations are tested in the course of developing a new product, the specifications of each formulation must be provided. Side-by-side comparisons should be made when trials are conducted with test formulations of the proposed active ingredient to allow the evaluator to use the performance data of all the formulations tested and the proposed formulation.

The test material should not be applied in a mixture with other pest control products, fertilizers, or other substances (other than adjuvants and diluents) except where the purpose of the trial is to obtain information on the performance of such mixtures, or where the inclusion of such products or substances would normally be considered good agricultural practice. Where two or more products in a tank mixture are being tested, each individual product should be included as a treatment in the same trial.

If the formulated product is to be mixed with other product(s) or spray adjuvant(s), test data must be produced to support the compatibility, efficacy, and safety to the host of the mixture. Physical compatibility can typically be confirmed by adding the component products to the application equipment tank as part of regular trials and checking for precipitation, corrosion, or other deleterious effects. Results may be summarized as a list of compatible/incompatible products and this information, including the order in which products should be added to the tank, should be reflected in the label directions for use. The proposed formulation must also be tested alone in order to establish the merit of additional components.

3.4 Application Rates and Lowest Effective Rate

In order to establish lowest effective rates (LER), it is essential to include a series of application rates in the efficacy research trials. For efficacy evaluation, results with the proposed label rate(s) (1×) and the one-half rate (0.5×) must be reported. Applicants are strongly encouraged to submit data for additional rates, including a three-quarter rate (0.75×) in order to fully evaluate data in the context of determining the lowest effective use rate. In trials to determine host tolerance, the inclusion of both the proposed application rate (1×) and twice the proposed rate (2×) are essential for herbicides. For insecticides, acaricides, and fungicides, inclusion of a greater than recommended rate is not a requirement for host safety unless phytotoxic effects are seen at the recommended

rate. Nevertheless, inclusion of a rate greater than recommended for these products may help to provide more confidence in the results obtained and is therefore suggested.

3.5 Selection of Trial Sites

Efficacy trials should be conducted in a variety of locations which span the environmental conditions, geographic regions, seasonal variation and soil zones in which the pest/crop combination are found and for which registration is sought. Efficacy data produced solely in one region may not be useful to support the registration for use in another region. For example, to support the registration of a product for use in apples, some trials must be conducted in each of the commercial apple production areas (e.g., BC, ON/PQ, Maritime provinces) in Canada or their equivalent areas in the U.S.A. Trial sites must also be representative of all the different production methods that could be encountered in Canada (e.g., potato production in southern Alberta under irrigation or in eastern Canada under natural climatic conditions).

A number of variables relating to the soil, such as texture, moisture content, fertility, organic matter content, and pH, may measurably influence the efficacy of the product, especially in the case of a soil treatment. Thus, these factors must be considered in selecting the sites of the tests, and recorded. The crops chosen for experimental sites may be specifically grown for experimental use or be part of a commercial operation, but in all cases should be managed according to normal commercial practice.

If results are consistent across trial sites in different production regions, then no further data may be necessary. However, if regional variation in product performance is found, then additional trials may be required in a particular region to refine application rates or timing to meet pest pressure in that area. For example, trials from sites in the U.S.A. which have climatic and production conditions similar to those in the proposed use regions of Canada (typically the northern states) may also be acceptable; however, the same principles apply. A brief scientific rationale is normally required, outlining the similarity between the foreign trial sites and specific Canadian production regions.

Laboratory or greenhouse bench trials (controlled environment tests) are required for proposed uses in sites such as greenhouses and mushroom houses. Greenhouse and laboratory studies conducted under appropriate testing conditions outside Canada can support proposed uses.

For proposed field uses, controlled environment tests are useful in preliminary screening of candidate pest control products, selection of one or more pest control products or rates for extensive field testing, and providing supportive data. Nevertheless, data generated under these conditions is not necessarily a realistic indicator of field performance. Conditions in the greenhouse, for example, can affect the structure of plant surfaces, as well as pest biology, thereby changing the efficacy and crop safety of a product. In some cases the crops grown in these conditions may be more susceptible to injury. Pesticide persistence may also differ indoors vs. outdoors due to differences in factors which can

influence pesticide efficacy, such as artificial light vs. sunlight and irrigation vs. rainfall. Therefore, controlled environment tests are considered supplementary to field trials.

3.6 Plot Size and Scale of Trial: Laboratory, Small-plot, Farm-level Trials

Determination of the most suitable plot size depends upon many factors, including the characteristics of the particular crop and the pests, diseases or weeds infesting it, the mobility of the target organism between plots, and the equipment used for treating and harvesting the crop. Since guard rows/areas often must be included, overall plot size should be sufficiently large to permit periodic sampling and evaluation of damage and crop yield in the central area of the plots. The individual plots must also be large enough to provide meaningful data from sampling to adequately represent the effects of the factors or variables being measured, and to minimize the effects of movement of target organisms from one plot to another. Untreated guard rows between plots can also reduce drift of product and pests from one plot to another. These rows may be of a taller or denser cultivar, or a more disease-resistant or spray-tolerant species. Guard rows are especially important if plot size is small. Physical barriers such as plastic sheets can also be used, and plots may also be planted farther apart to provide a distance break. Untreated guard rows in herbicide trials reveal the degree of uniformity of weed infestation at the experimental site and help the researcher when rating the performance of each treatment.

For practical reasons, plot sizes are usually as small as possible while still assuring an adequate infestation of the organism to be controlled. The larger the plot, the less the interplot interference. On the other hand, where the difference in levels of infestation between adjacent plots is greater, the interplot variation is also greater, thereby necessitating more replicates. It is normal for there to be a progression in plot size as product testing proceeds from controlled environments, to nursery or small field plots, through to large plots and commercial scale testing.

Whenever possible or practical, the results obtained in small plot tests should be confirmed by data obtained in operational trials under normal field-use conditions. These large trials serve the useful purpose of demonstrating the performance of the product under varying commercial conditions using typical application equipment and techniques. Data obtained from these large trials should be considered as complementary to those obtained in the small plot tests. To make the results more useful, a small untreated strip should be kept to aid in comparative efficacy evaluation. In some cases, however, it may be entirely appropriate to submit data only from well-conducted field scale trials conducted with commercial equipment under a Research Permit (see DIR98-05). Data may be generated under these conditions for uses such as fertilizer impregnation or when products are applied in liquid fertilizer solution.

Additional guidance of a general nature on plot size, shape, and the need for borders can be obtained from EPPO Guideline PP 1/152(2) (EPPO, 1999). Guidance on minimum plot size can also be obtained for some crop/pest combinations in individual EPPO guidelines (EPPO, 1997a,b, 1998, 1999).

3.7 Application Technique and Sequential Applications

The effectiveness of a pest control product can often be influenced by the way the treatment is applied. Therefore, the methods of application used in the test and those given in the label claim directions must be in agreement. A detailed record should be kept of application equipment (including nozzle type, spray pressure, and spray quality); carrier volume; the placement of the pest control product; date of treatment and harvest; treatment time in relation to number of days before or after planting, emergence, or harvest; the stage of growth of the crop when treatment was made; the stage of growth or expected appearance of the pest at treatment time; duration of exposure to pest control product treatment; treatment-to-observation intervals commonly referred to as days after treatment (DAT).

Sequential applications

Sequential applications can be defined as either split or multiple applications of a pest control product. Sequential applications of the same pest control product may be required under specific conditions where better control can be achieved over a prolonged period. The sequential application of herbicides is usually done as a result of failure of the first application or when a second flush of weeds occurs. The sequential application(s) must occur within the label growth stage of the crop and weeds. Sequential treatment also refers to application of two different herbicides that cannot be tank-mixed because of antagonism or crop injury. Sequential applications can also apply to a pest control product which is applied at intervals throughout the season, e.g., a protectant fungicide applied weekly to control potato late blight (multiple application).

In all cases, the purpose of the proposed use pattern should be clearly explained and trials should demonstrate that the timing, rate, interval between applications, and role of the product are justified. It is preferable that the trials be conducted with treatments in the same sequence as that which is being proposed, and in comparison with commercial standards applied according to typical practice. However, several comparison trials to test different variables together with a rationale, for instance showing that two half rate applications give better control than a single full rate application, or that weekly applications are more effective than biweekly, may also be acceptable.

Application method and water volume

The method and conditions of application should be the same as, or as similar as possible to, that proposed for the product. The spray application pattern used in trials should be similar to that used in commercial practice, both in particle size and distribution, and in deposition on the treated surfaces. For field and horticultural crops, it is recommended that nozzles which produce a Medium to Coarse spray quality (ASAE, 1999; Southcombe, *et al.*, 1997) be used to develop efficacy data, as these are most commonly used in commercial practice. The spray volume and diluent should be as recommended for commercial use except where these factors are being evaluated. When considering the suitability of low drift application methods, the conventional application method should be compared to an air-induced nozzle in side-by-side tests. For herbicides particular

emphasis should be placed on grassy weeds and some difficult-to-wet weeds which may exhibit reduced retention of coarser sprays. The rules for bridging data explained elsewhere in this document would apply.

The water volumes proposed on the product label should be considered to be a prerequisite for the protocols of trials to demonstrate the efficacy and crop safety of a product. For situations where a dilution rather than a specific volume of water per hectare is to be recommended, trials should reflect the recommendation. Where appropriate, information on crop or canopy size should be provided. It is accepted for most field and horticultural crops that the range of water volumes, using standard hydraulic nozzles, is 200–400 L/ha. A water volume of 100 L/ha is used for most herbicides in the prairie provinces, however. Trial data using any water volume within this range is acceptable for such label recommendations. For all other label recommendations there is a need for trial data using the recommended water volumes or a rationale as to why trial data using a different volume are applicable.

Timing and treatments

The timing to be recommended in label claims should be tested. Inclusion of earlier and later timings in test protocols, where appropriate, may provide additional useful information. Where repeated applications are the norm, the timing of the first application should be that expected to be recommended for the product being tested. Different frequencies of application may be compared. The optimum interval between applications may have to be established by experimentation. Efficacy should be measured after each of the sequential treatment to determine the need and optimum timing for subsequent treatments. The criteria used to determine the need for subsequent treatment (i.e., treatment threshold) should be clearly defined.

3.8 Application Technology

As application methodology can affect the overall performance of a pest control product, data are required to support the efficacy and crop tolerance associated with each different method of application (e.g., to the ground by in-furrow or banded application, soil drench, chemigation, seed treatment, foliar, air blast, aerial).

When it is desired to expand label directions to include another method of application, supporting trials must compare the relative efficacy of the application methods. Where side-by-side comparisons are made of the efficacy of registered and proposed methods, fewer trials than would otherwise be required on representative use sites may be needed to allow bridging from one application method to the other for all label claims.

In conducting aerial trials, consideration should be given to the dimensions of the trial plots. As there is usually considerable overlap of adjacent swaths, a plot consisting of a single swath will not reflect deposit under operational conditions. There should be a minimum of three swaths, but five is preferable. When flow to the boom is switched on, it usually takes at least two seconds for full operating pressure to be attained and stabilized. Spray blocks should be long enough to ensure that assessment plots are not located in this region of uncertain application rate. Using swath markers is important in research tests to minimize stripping. These are missed areas of a site which did not receive treatment due to application error.

One of the most common challenges in aerial trials is uncertainty about the application rate. The researchers should perform their own calibration (speed, swath width, and flow rate). A final check of application rate should also be made by dividing the amount of pest control product used by the area treated.

3.9 Performance Assessment Parameters

Efficacy

Regardless of the type of assessment chosen, the sampling methodology, including timing, should be described clearly in a "materials and methods" section of the trial report. Several parameters may be used to measure efficacy of pest control products. Observations should be scored using quantitative and qualitative parameters relevant to the particular crop/pest combination. Direct measurements can be made of pathogen populations and pest incidence, and indirect measurements made of numbers of plants infected/infested, severity of symptoms or damage per plant or plot and plant survival. Other factors that may be used to assess performance include plant height, dry weight and gross yield, appearance of seeds or fruit, storage characteristics, and the quantity and quality of marketable yield. Pretreatment conditions and population pressures also provide valuable information regarding the level and type of control provided by the test product.

The efficacy of the product should be assessed against a commercial standard and both should be compared with an untreated control to provide a measure of the degree of pest infestation, or development, and of control. Parameters such as population reduction described as percent mortality should be corrected to account for mortality in untreated control plots to provide values for percent control.

Effects of treatment on the host

Applications of pest control products may result in injury to the host at certain dosage rates or under certain conditions (e.g., drought conditions). Injury to host plants (phytotoxicity) may appear as chlorosis, malformed plant parts, leaf burning, wilting, death of plant parts or entire plants, delayed emergence or maturity, reduced growth, reduced yield, or other abnormalities. Any injury observed, including any effect due to treatment on maturity date, size, quality, and appearance of edible parts, should be noted and described along with an explanation of likely contributing factors.

Effects on non-target organisms relevant to pest management
The use of a pest control product could have beneficial or hazardous effects to nontarget species such as beneficial arthropods (e.g., predators, parasites) and microorganisms. While these side-effects may not have been considered in designing efficacy trials, such information should be recorded, assessed, and reported from the efficacy trials where observed.

3.10 Pesticide Combinations/Tank-Mixing

Pesticide combinations refer to the use of two or more products at the same time, including tank-mix treatment and concurrent application from separate spray tanks connected to the same set of spray nozzles. This includes seed treatment products which are applied to seed in the same operation. Use of pesticide combinations may result in additive, synergistic, or antagonistic effects. Product labelling which recommends or implies the use of pesticide combinations may require supporting physical compatibility information and efficacy data (including phytotoxicity). Efficacy and crop tolerance studies should be conducted such that each component is tested separately as well as the combination. See Section 3.3 "Test Substances and Compatibility Tests."

In examining products in a tank-mix combination it is essential that data be provided to demonstrate that pest control is maintained for the existing labelled pests for the relevant active ingredients and to quantify any loss of control that may result from the active ingredient combination. This can only be accomplished by reporting the proposed tank-mix treatment in direct comparison to the component active ingredients applied alone.

If the rate of any of the tank mixture components is reduced below the label rate of the component applied alone, claims of control/suppression of pests on that component product label can only be accepted upon the submission of adequate data demonstrating efficacy at the reduced rate when applied in tank mixture. It is helpful to clarify in the summary whether the proposed tank-mixes are for convenience (two actives have no overlap in range of pests controlled) or improved activity (synergism between actives allows one or both to be mixed at a reduced rate).

3.11 Adjuvants

Products with labelling that recommends the addition of separately packaged adjuvants to the spray tank should be supported with data indicating benefits and detrimental effects, if any, of the adjuvants. Efficacy studies should be designed to test specific adjuvant/pesticide/crop/pest situations and the product should be labelled as such. The trials should include a pesticide-alone treatment (without adjuvant) in order to assess merit/value of adding an adjuvant. If a range of adjuvant rates is recommended, the maximum and minimum rates should be evaluated in conjunction with the intended pest control product.

3.12 Pest Control Products Used With Fertilizers

Pest control products may be used in tank mixtures with fluid fertilizers or be impregnated onto dry fertilizers. When a pest control product and fertilizer combination is sold as one product in a package, the product is subject to regulation under the *Fertilizers Act* and Regulations; the pest control product itself must have been registered under the PCPA and Regulations. When a pest control product is sold separately for use as a tank-mix with fluid fertilizers or for impregnation onto dry fertilizers, this use is subject to regulation under the PCPA and Regulations. In either case, field test data must be provided to support the efficacy and crop tolerance of the combination. Efficacy trials should be conducted for the pest control product alone as well as in combination with the specific fertilizer(s). Crop tolerance to post-emergence application of tank mixtures with fertilizers is of particular concern due to the possibility of increased crop sensitivity to the combination.

In the case of using fluid fertilizer as a carrier for pest control product application, field test data should indicate spray volume, fertilizer analysis, efficacy and detrimental effects, on a crop-specific basis.

In the case of fertilizer impregnation, the main purpose of the submitted data package would be to demonstrate that an even application distribution is maintained to prevent any effect on tolerance and efficacy with the impregnated product.

3.13 Crop Tolerance

For herbicides, crop tolerance data from at least ten dedicated crop tolerance trials conducted over two or more years are required to demonstrate crop safety of a new end-use product containing a new active ingredient. Additional trials are required if there is evidence of phytotoxicity or variability in the level of phytotoxicity, or if the trials submitted for review are not dedicated crop tolerance trials but rather efficacy trials with crop tolerance observations. Dedicated crop tolerance trials should be designed to allow the direct comparison of the crop tolerance response of several cultivars for a crop to the proposed treatment applied at the maximum proposed 1× and 2× rates of application, with a commercial standard and a weed-free check treatment. Design of field trials to facilitate both grass and broadleaf weed control allows for both qualitative and quantitative measures of tolerance in a nearly weed-free setting. Qualitative measurements should include crop injury assessments throughout the season following application, with evaluations conducted at 7–14, 21–35, and 42–56 days after treatment. Quantitative measurements should include crop yield data collected from all trials (regardless of the presence or absence of visual crop injury).

3.14 Rainfastness

Adding a rainfast statement to a product label (the period of time following application when rainfall will not negatively affect efficacy of a foliar applied product) requires the submission of efficacy data to support such a claim. Considering the difficulties in conducting rainfastness trials under field conditions, laboratory data in which an adequately simulated rainfall event was used, will be accepted. Field trials specifically designed to simulate typical rainfall events following application should be conducted to demonstrate the duration of the rain-free period following application required to avoid loss in efficacy of herbicides. For fungicides, lab or field data are required to show that residues of the product are detectable on foliage and product efficacy is not reduced as a result of simulated rain during the proposed rainfast period. General statements or adjectives implying that the formulation is persistent or rainfast are not acceptable.

4.0 Reporting and Preparation of Efficacy Data Package

To facilitate efficacy evaluation for registration purposes, it is essential that the data submission be presented in an orderly manner and contain complete and accurate information. Guidance regarding the organization and formatting of efficacy, crop tolerance, and rotational cropping data submissions is presented in PRO98-02, *Organizing and Formatting a Complete Submission for Pest Control Products*.

Submissions of efficacy, crop tolerance, and rotational cropping data must include the complete study report(s) for individual trials, as well as summaries of the results for the entire data set.

4.1 Reporting of Individual Trial Results

Complete study reports are required for each of the individual efficacy, crop tolerance, and rotational crop trials. All details of the trials should be reported, giving particular emphasis to variables that relate to the proposed label directions and limitations. Such details may include, but are not limited to, the following, when appropriate:

- the objectives of the trial;
- the location of the trial site;
- chemical name and formulation;
- target pest organisms and population levels;
- host, e.g., crops and cultivars;
- growth stage of the host and/or the pest;

- soil factors (e.g., type, texture, percent organic matter, pH, moisture content/deficit);
- experimental design, size, and number of plots;
- application dates and rates;
- application method and equipment, type and size of nozzles, operating pressure, etc.; for aerial applications, details of aircraft type and model, speed, flying height, swath width, boom position and width, number of nozzles, nozzle type and orientation (e.g., CP-03, 30° deflector, 0.078 orifice), flow rate, wingspan or rotor length, and distance from wing or rotor tip to outermost nozzles should be reported;
- volume of spray carrier, and water conditions (e.g., pH, hardness) if water is used;
- adjuvants, fertilizers or other spray additives, where applicable;
- weather conditions during and after treatment (e.g., precipitation, temperature, relative humidity, wind speed and direction, atmospheric stability); N.B.: extreme weather conditions such as severe and prolonged drought, storms, or hail occurring prior to or after application, which may influence product performance or pest populations, should also be reported;
- cultural practices including treatment of the plots with other pest control products;
- dates of assessment;
- size and frequency of sampling;
- quantity and quality of yield of the treated commodity;
- side-effects (positive or negative);
- statistical analysis and data assessment;
- performance evaluation including interpretation, discussion and conclusions that relate to label claims; and
- name of the responsible researcher and organization.

4.2 Reporting of Data Summaries and Conclusions

Submissions must include summaries of the submitted data and the conclusions related to the proposed label claims. The summaries should consist of the following elements:

4.2.1 Description of Proposed Treatment

The proposed pest control product use must be clearly described indicating:

- crop(s)/site(s)
- pest control claims with an indication of level of control, i.e., control, suppression
- product proposed for use (formulation and guarantee)
- application rate (g or kg active ingredient per hectare)
- adjuvant or any other spray solution additive (if any) and its rate
- application method (spray, granular, furrow, etc.)
- number of applications per season and interval between applications
- application timing relative to crop growth stage
- application timing relative to pest growth stage
- pre-harvest interval
- spray volume applied (as appropriate)
- nozzle type and spray quality (e.g., flat fan nozzle producing a Medium spray)
- for rotational cropping claims, the appropriate interval after which a rotational crop can be planted

4.2.2 Summary of Research Results

The summary of research results highlights the conclusions that can be drawn from the data reported. The conclusions must be clear and precise, and drawn on the basis of data analysis and evaluation of all reported trials. There is an opportunity here to explain trials or years where results were not as expected, and to relate experimental results to typical commercial conditions. The results obtained with the proposed treatment should be compared to the other treatments evaluated in the supporting trials to substantiate that the proposal is valid. In order to justify the proposed rate of application, the performance of

the proposed treatment on specific pests (1× rate of application) should be discussed relative to reduced rates of application (e.g., 0.5×, 0.75×). Crop phytotoxicity of the proposed rate (1×) compared to the 2× rate for each proposed crop should be discussed. For rotational cropping studies, results of crops grown in treated soils should be compared to those grown in soils which did not receive pest control product application.

In the summary of results, it is particularly important to highlight where bridging data or extrapolation are used and to clearly discuss the results of the proposed new use compared to the registered treatment that is supported by a full data package.

4.2.3 Data Summary Tables

Efficacy and crop tolerance data must be summarized using the format outlined in Appendix I (Tables 1 and 2). A separate summary should be provided for each new efficacy, crop tolerance, and rotational cropping claim. Note that each submitted study will typically occupy more than a single row on a table, e.g., one row reports the proposed treatment result for a specific parameter evaluated at a specific evaluation date, and another row reports the results for a comparison treatment for the same parameter and evaluation date. All relevant treatments, all parameters, and all evaluation dates are reported as line entries in the table. Reporting of data in this spreadsheet format allows sorting (e.g., by soil type) by the reviewer if required. For fungicides, additional columns for multiple performance assessment (e.g., for leaves, fruit, or several assessment dates) can sometimes be accommodated by reporting basic information under "Comments." Comments on any study/row can also be added as footnotes to a table. These comments are useful in providing short explanations of why outlier results, e.g., treatment failure, were observed. Applicants should ensure that individual trial reports are also submitted for each of the trials noted in the summary tables.

Summary Tables for Efficacy Data

Efficacy summary tables are required for each pest proposed on the label. If different conditions of use for the pest control product are proposed such as application timing (PPI and PRE) or conventional tillage vs. no-till, each condition will require a separate summary table. Each trial reported in the efficacy table should include entries for the proposed treatment (1× rate of application), comparison treatments (e.g., 0.5×, 0.75× and a commercial standard) and an untreated control. Where the bridging approach has been used, the proposed treatment, the known registered treatment, and the untreated control are sufficient. Data entries should be sorted by crop within a given table.

For tank mixtures using registered rates of each pest control product component, the proposed tank-mix treatment (1×), each tank-mix component treatment applied alone (1×), a commercial standard, and an untreated control should be reported. For tank mixtures proposing a lower rate of one or all of the tank-mix partners, the following treatments should be reported for each of the trials summarized in the table: the proposed tank-mix treatment, each tank-mix component used alone at the same rate at which it is used in the tank-mix treatment, a commercial standard and an untreated

control. A separate summary table for each pest proposed for control/suppression with the tank-mix should be provided.

Summary Tables for Crop Tolerance Data

Separate crop tolerance summary tables are required for each crop proposed on the label. Summary tables for crop tolerance or rotational cropping assessment must include entries for the proposed treatment (1×), rates higher than the proposed rate (e.g., 2×), and a commercial standard. Where the bridging approach has been used, the proposed treatment and the known, registered treatment are sufficient. Yield data may be reported as a percent of the untreated and/or commercial standard treatment. If different conditions of use for the pest control product are proposed such as application timing (preplant incorporated (PPI) and preplant (PRE)) or conventional tillage vs. no-till, each condition will require a separate summary table within each proposed crop. Tables should be sorted by variety within crop to allow for detection of varietal differences in the crop tolerance profile.

4.2.4 Frequency Distribution Tables

Frequency Distribution Tables must accompany the data summary tables for efficacy and crop tolerance where there are more than three trials per claim. Templates for these tables are presented in Appendix II (Tables 1 and 2). A frequency distribution table should be reported for each pest claim, each crop proposed, or for each rotational crop. If tank mixtures or various conditions of use are proposed (e.g., PPI, PRE), frequency distribution tables should be produced for pests/crops within each tank mixture/condition. The purpose of the frequency distribution table is to provide an overall summary of the trials reported in the data summary tables. The performance of the proposed treatment is compared to the relative performance of other treatments (e.g., 0.5×, 0.75×, 2×, commercial standards). The mean performance of each treatment is reported, and, importantly, the variability in performance across all trials is evident.

Where the data set contains some trials which assessed only the proposed treatment (no comparison or bridging treatments) and other trials which assessed the proposed treatment and other treatments (i.e., properly designed bridging trials), it is recommended that two frequency data tables be produced, one reporting the results for the proposed treatment from all available data, the other reporting the results only from trials where the proposed treatment is compared directly (i.e., paired comparisons) to a bridging treatment.

4.3 Overview

4.3.1 Objectives

The value data package may consist of efficacy and crop tolerance trials designed specifically to address Canadian requirements, indirect data generated for other purposes such as to compare a range of products or scientific literature, a scientific rationale for a waiver of data, or a combination of these (see Section 2.1.1). Once the data package is developed, the applicant should review it to verify that all proposed label claims are adequately supported. In all cases it is necessary to describe the approach being taken to meet Canadian requirements and how the data pieces contribute to this. The objectives of the research program should be outlined in the Value Summary and, in more detail, in the Efficacy Summary and Non-Safety Adverse Effects Summary. Where data are not provided but some other method of addressing requirements is used, the rationale should be clearly stated in these summaries. The PMRA evaluator should be able to follow the interpretation of the data intended by the research coordinator.

4.3.2 Acceptability of Studies

As noted in Sections 2.1 and 2.2, acceptable studies (valid trials) are those in which there was adequate pest pressure and where the product was shown to be effective and safe to the crop. Should all of these criteria not be met, the trial results may still serve a purpose in confirming crop tolerance in the absence of a pest or in highlighting conditions under which the product is less effective or is phytotoxic. These trials should therefore be included in the appropriate DACO (data code) but should not be presented as supporting data for efficacy in the Value Summary.

4.3.3 Location, Duration, Number of Tests

Section 2.2 provides guidance on the appropriate location, duration, and number of tests for each product type. It would be useful for the applicant to compare the proposed data package with these requirements and where the number of trials appears to be insufficient, provide an explanation or a scientific rationale to compensate for this.

4.3.4 Expected Level of Control

Section 2.2 provides guidance on the appropriate levels of efficacy of pest control for each product type. It is usually more efficient for the applicant to decide which claim (i.e., suppression or control) is supported by the data and to propose this for the draft label, rather than to overstate the claims and have them prove unacceptable to the PMRA evaluator.

4.3.5 Justification of Label Rate, Timing, Frequency

As noted in Section 3.3, the purpose of testing the product at rates below those proposed for the label is to demonstrate that the proposed rates are the lowest which will work and are therefore necessary for effective control. Interpretation of trial results with respect to rate should be presented in the Efficacy Summary and should show that the proposed rate is justified. Where efficacy is equivalent for proposed and lower rates, but other factors such as high pest pressure may justify the need for the proposed rate, supporting information, such as commercial standard or expert opinion, should be provided and the rationale clearly stated. A similar approach should be taken in supporting the timing and frequency of product application as proposed on the draft label. If the maximum number of applications requested is unlikely to be supported by the submitted data, then it may be useful to suggest a minimum number which would be consistent with typical crop production practices.

4.3.6 Crop Tolerance

As noted in Section 3.13, application rates above those proposed on the draft label are tested for the purpose of ensuring that operational errors in product application, such as overlapping sprays, do not result in crop injury. This requirement may be waived in situations where it can be documented that over-application is not a possibility in practice (e.g., certain seed treating equipment). The interpretation of data from applications made at rates above those proposed or any scientific rationale for a waiver of data requirements should be presented in the Non-Safety Adverse Effects Summary.

List of Abbreviations

a.i.	active ingredient
ASAE	American Society of Agricultural Engineers
BBCH	BASF, Bayer, Ciba-Geigy and Hoechst
CEC	Cation Exchange Capacity
EPPO	European and Mediterranean Plant Protection Organization
DAT	days after treatment
IPM	Integrated Pest Management
IR-4	Interregional Research Project No. #4
LER	lowest effective rate
NRA	National Registration Authority for Agricultural and Veterinary Chemicals, Australia
PCPA	*Pest Control Products Act*
PCPR	Pest Control Products Regulations
PMRA	Pest Management Regulatory Agency
POST	post treatment
PP	preplant (EPPO acronym)
PPI	preplant incorporated
PRE	pre-emergent
UK DEFRA	United Kingdom Department for Environment, Food and Rural Affairs
URMULE	User Requested Minor Use Label Expansion
U.S.A.	United States of America
U.S. EPA	United States Environmental Protection Agency

Appendix I Trial Summary Tables

Table 1 Trial Summary Table for Herbicides

(for efficacy — one table per proposed weed per use;
for crop tolerance — one table per proposed crop per use;
for crop yield — one table per proposed crop per use)

Trial Identification						Crop Description			Soil			Application									Weed at Application		Evaluation		
Trial Ref. No.	Researcher & Affiliation	ECW report #	Year	Site	Prov	Crop	Variety	Type	Type	% OM	pH	Vol. (L/ha)	Date d/m/y	Crop GS	Herbicide Treatment	Herb. rate	Adj.	Adj. rate	Fert.	Fert. Rate	Weed GS	Weed Density	Parameter	DAT	Rating
R[1]	R[2]	CR[3]	R[4]	R[5]	R[5]	R[6]	CR[7]	CR[7]	R[8]	CR[9]	CR[10]	CR[11]	R[12]	CR[13]	R[14]	R[15]	CR[16]	CR[17]	CR[18]	CR[19]	CR[20]	CR[21]	R[22]	R[23]	R[24]
EXAMPLE																									
1	RF, CYC	92345	93	Regina	SK	barley	Manley	2-R	loam	5	6.7	132	6/7/92	13	HerbA	0.25	AdjX	1%	28-0-0	1%	13	16	CHEAL	35	82
1	RF, CYC	92345	93	Regina	SK	barley	Manley	2-R	loam	5	6.7	132	6/7/92	13	HerbB	0.1	-	-	-	-	13	16	CHEAL	35	96
1	RF, CYC	92345	93	Regina	SK	barley	Manley	2-R	loam	5	6.7	132	6/7/92	13	HerbA + HerbB	0.25 + 0.10	AdjX	1%	28-0-0	1%	13	16	CHEAL	35	100

R = Required element
CR = Conditionally Required element

Footnotes:

1. Trial reference number. Assign a number to each trial for easy reference in the data submission.
2. Researcher name and affiliation. Trial author/cooperator and affiliation (company, public institution).
3. Expert Committee on Weeds Research Report identification (if applicable).
4. Year the trial was conducted. Trials should be summarized and grouped by year.
5. Trial site (nearest town, village) and province where the trial was conducted.
6. Crop on which the trial was conduced. Trials conducted on the same crop should be listed one after the other.
7. Varietal name of the crop evaluated and variety type (e.g., 2-row or 6-row barley; bread or CPS wheat).
8. Soil type or classification (e.g., clay loam, sandy loam).
9. Soil organic matter content (percent). Required for soil-applied herbicide and herbicide with residual soil activity.
10. Soil pH. Required for soil-applied herbicide and herbicide with residual soil activity.
11. Expressed as litre of spray solution per unit area (e.g., L/ha). Not required for herbicides applied as granules (not mixed with water).
12. Date the herbicide treatment was applied. For split applications report all dates.
13. Crop growth stage at application using standardized system (e.g., BBCH). Not required for PP, PPI, PRE treatments.
14. Active ingredient common name or code name and formulation code should be identified. Summarized treatments should include all rates evaluated, untreated control and commercial standard for comparison purposes.
15. Application rate(s) applied in metric units in terms of active ingredient per unit area (e.g., g a.i./ha) or concentration (e.g., g a.i./1000 L water). For split applications indicate rate applied at each application.
16. Adjuvant trade name. Required only if adjuvant use is proposed with the herbicide.
17. Adjuvant application rate (usually % v/v or L/ha). Required only if adjuvant use is proposed with the herbicide.
18. Fertilizer type applied (e.g., 28-0-0) in the spray solution. Required only if fertilizer use is proposed with the herbicide.
19. Fertilizer application rate (usually % v/v or L/ha). Required only if fertilizer use is proposed with the herbicide.
20. Weed growth stage at application. Usually the true leaf number present or standard growth stage system (e.g., BBCH). Not required for PPI treatments.
21. Weed density at application. Count (no./m^2) or % cover of the weed present at application.
22. Parameter evaluated (e.g., BAYER weed code, crop injury, yield compared to untreated, yield compared to commercial standard).
23. Days after treatment (DAT). Indicates interval (in days) between treatment application and performance assessment. If split application used, indicate DAT from the final application.
24. Rating of the parameter evaluated (e.g., percent control, yield expressed as a percent of the untreated).

Table 2 **Trial Summary Table for Insecticides, Acaricides, and Fungicides**
(For efficacy — one table per crop/pest use;
for crop tolerance — one table per crop)

Name of crop/commodity: _____
Name of pest (for efficacy): _____

Ref. No.	Year, Location, Author/Cooperator	Treatment	Rate	Timing of Application	Performance Assessment	Days After Treatment	Yield	Comments
R[1]	R[2]	R[3]	R[4]	R[5]	R[6]	R[7]	CR[8]	CR[9]

R = Required element
CR = Conditionally Required element

Footnotes:

1. Assign a number to each trial for easy reference in the data submission.
2. To allow for quick review of regional representation of data, include author/cooperator.
3. State name of product (identify formulation) used in the trial, including control and commercial product comparisons, if available, and application method, e.g., in-furrow, soil, foliar.
4. Rates must be expressed in metric units in terms of active ingredient per unit area, e.g., g a.i./ha, or concentration, e.g., g a.i./1000 L water.
5. Timing should be expressed in terms of calendar date as well as developmental stage of both the crop/commodity (e.g., plant; pink bud stage) and pest (e.g., egg, adult), where applicable.
6. Indicate percentage control of the pest or, where appropriate, another assessment index. A description of how "percentage control" figures were calculated must be included in the submission.
7. Days after Treatment (DAT): Indicates interval, in days, between treatment application and performance assessment.
8. Where relevant, effects of treatment on yield should be used as a measure of performance and compared to untreated control.
9. Any comments relevant to the results, e.g., unusual conditions resulting in failure of the trial. This column can be deleted and comments included as footnotes instead.

Example of Completed Table 2, Trial Summary Table for Insecticides, Acaricides, and Fungicides

Name of crop/commodity: Apples
Name of pest (for efficacy): European red mite

Ref. No.	Year, Location, Author/ Cooperator	Treatment	Rate (g a.i./ha)	Timing of Application	Performance Assessment (Mean # nymphs/leaf)	Days After Treatment	Comments
1	1999, Vineland, Ontario, J. Doe	Insecticide X	200	28/07/99	0.6	7	Treatments were applied as a dilute spray to point of run-off (3000 L/ha) on 21/07/99. On the day of treatment, populations of mites averaged 9.0, 10.1, 8.9, and 11.4 nymphs per leaf for the Insecticide X (200 g a.i./ha), Insecticide X (100 g a.i./ha), Standard and Untreated plots, respectively.
1	1999, Vineland, Ontario, J. Doe	Insecticide X	100	28/07/99	0.8	7	
1	1999, Vineland, Ontario, J. Doe	Standard	450	28/07/99	0.5	7	
1	1999, Vineland, Ontario, J. Doe	Untreated	-	28/07/99	15.7	7	
1	1999, Vineland, Ontario, J. Doe	Insecticide X	200	28/07/99	1.1	14	
1	1999, Vineland, Ontario, J. Doe	Insecticide X	100	28/07/99	8.2	14	
1	1999, Vineland, Ontario, J. Doe	Standard	450	28/07/99	0.9	14	
1	1999, Vineland, Ontario, J. Doe	Untreated	-	28/07/99	22.7	14	

Appendix II Frequency Distribution Tables

Table 1 **Frequency Distribution Tables for Efficacy Assessment**
(one table per pest per use per evaluation date)

Examples:

Table 1a. Proposed end-use product containing a new active ingredient

Treatment	Number of Trials					Mean control* (%)
	Frequency Distribution of Pest Control Assessment				n	
	100–90%	89–80%	79–70%	<60%		
Pest control product A @ 0.5×						
Pest control product A @ 0.75×						
Pest control product A @ 1×						
Commercial Standard @ 1×						

*Note: Non-representative results should be excluded from the summary with explanations, e.g., "results from trial #91-003 were excluded from the summary because heavy rainfall immediately following application rendered the treatment ineffective."

Table 1b. Proposed new formulation of a registered end-use product with identical uses proposed (bridging trials)

Treatment	Number of Trials					Mean control (%)
	Frequency Distribution of Pest Control Assessment				n	
	100–90%	89–80%	79–70%	<60%		
new formulation pest control product A @ 1×						
registered formulation of pest control product A @ 1×						

Table 1c. Proposed tank mixture of Pest Control Product A and Pest Control Product B (both already registered on the crop)

Treatment	Number of Trials					Mean control (%)
	Frequency Distribution of Pest Control Assessment				n	
	100–90%	89–80%	79–70%	<60%		
Pest control product A @ 1× + Adjuvant C @ 1%						
Pest control product B @ 1×						
Pest control product A @ 1× + Pest control product B @ 1× + Adjuvant C @ 1%						

Table 2 Frequency Distribution Table for Adverse Effects on Host Crop
(one table per host crop per use per evaluation date)

Examples:

Table 2a. Proposed end-use product containing a new active ingredient

Treatment	Number of Trials					Mean injury (%)
	Frequency Distribution of Pest Control Assessment				n	
	0%	1–4%	5–10%	>10%		
Pest control product A @ 1×						
[Pest control product A @ 1×] × 2 double application						
commercial standard @ 1×						

Table 2b. Proposed tank mixture of Pest Control Product A (graminicide herbicide) and Pest Control Product B (broadleaf herbicide)
(both already registered for use on the crop alone)

Treatment	Number of Trials					Mean injury (%)
	Frequency Distribution of Pest Control Assessment				n	
	0%	1–4%	5–10%	>10%		
Pest control product A @ 1× + Adjuvant C @ 1%						
Pest control product B @ 1×						
Pest control product A @ 1× + Pest control product B @ 1× + Adjuvant C @ 1%						
[Pest control product A @ 1× + Pest control product B @ 1× + Adjuvant C @ 1%] × 2 double application						

Appendix III References[1,2]

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DIR97-02. PMRA Regulatory Directive. *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals.* September 29, 1997.

DIR98-01. PMRA Regulatory Directive. *Good Laboratory Practice.* July 27, 1998.

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DIR99-06. PMRA Regulatory Directive. *Voluntary Pesticide Resistance Management Labelling Based on Target Site/Mode of Action.* October 6, 1999.

DIR2001-01. PMRA Regulatory Directive. *User Requested Minor Use Label Expansion.* February 14, 2001.

DIR2001-02. PMRA Regulatory Directive. *Guidelines for the Registration of Microbial Pest Control Agents and Products.* March 30, 2001.

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PRO2000-01. PMRA Regulatory Proposal. *Notification/Non-Notification.* February 16, 2000.

Southcombe, E.S.E., Miller, P.C.H., Ganzelmeier, H., Van de Zande, J.C., Miralles, A, and Hewitt, A.J. 1997. The international (BCPC) spray classification system including a drift potential factor. Proc. 1997 Brighton Crop Prot. Conf. - Weeds 5:371–380.

1. Order forms for EPPO documents can be obtained from EPPO (European and Mediterranean Plant Protection Organization) at http://www.eppo.org/ or through OEPP/EPPO, 1 rue Le Nôtre, F-75016 Paris, France; Tel: +33(0) 1 45 20 77 94; Fax: +33(0) 1 42 24 89 43; E-mail: hq@eppo.fr

2. PMRA Regulatory Directives and Regulatory Proposals can be obtained through www.hc-sc.gc.ca/pmra-arla/

Appendix IV Definitions

Bridging data: a set of trials used to directly compare a proposed new use to an established use on a registered label or to a proposed use that is supported by full data.

Commercial Standard: treatment that is registered in Canada and commonly used on the crop/pest combination, and applied in the trial at the registered use rate.

Control: the pest control product consistently reduces pest numbers or pest damage to a commercially acceptable level.

Disease control: providing at least a 60% reduction in disease incidence or severity.

Economic threshold: as a pest population rises at a particular time and place, it is the maximum pest population that can be tolerated, or the point at which the resultant damage justifies taking control measures.

Efficacy: the ability of a pest control product to fulfil the claims made for it on the product label. This includes the extent of control of the pest problem and considers any adverse effects on the treated site.

Extrapolation: describes a situation where a full data set has been submitted for established or proposed pest control claim(s) and additional claims are then considered based only on scientific rationales and not on additional data.

Merit: a product has merit if efficacy data demonstrate that it is effective in controlling the pests claimed.

Minor use: a necessary use of a pest control product for which the anticipated volume of sales is not sufficient to persuade the manufacturer to register and sell the product in Canada.

Sequential: sequential applications are either split or multiple applications of a pest control product.

Stripping: missed areas of a site which did not receive treatment due to application error.

Suppression: *consistent* pest control at a level which is not optimal but is still of commercial benefit. "Suppression" is not used for products which show highly variable performance between trials.

Value: a product normally has value if data demonstrate that control of the pest provides a benefit or is needed.